

Package leaflet: Information for the patient

Sunlenca 464 mg solution for injection lenacapavir

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sunlenca is and what it is used for
2. What you need to know before you are given Sunlenca
3. How Sunlenca is given
4. Possible side effects
5. How to store Sunlenca
6. Contents of the pack and other information

1. What Sunlenca is and what it is used for

Sunlenca contains the active substance lenacapavir. This is an antiretroviral medicine known as a capsid inhibitor.

Sunlenca is a long acting medicine and **is used in combination with other antiretroviral medicines** to treat type 1 human immunodeficiency virus (HIV), the virus that cause acquired immunodeficiency syndrome (AIDS).

It is used to treat HIV infection in adults with limited treatment options (for example when other antiretroviral medicines are not sufficiently effective or are not suitable).

Treatment with Sunlenca in combination with other antiretrovirals reduces the amount of HIV in your body. This will improve the function of your immune system (the body's natural defences) and reduce the risk of developing illnesses linked to HIV infection.

2. What you need to know before you are given Sunlenca

Do not receive Sunlenca

- If you are allergic to lenacapavir or any of the other ingredients of this medicine (listed in section 6)
- If you are taking any of these medicines:
 - **rifampicin**, used to treat some bacterial infections such as tuberculosis
 - **carbamazepine, phenytoin**, used to prevent seizures
 - **St. John's wort** (*Hypericum perforatum*), a herbal remedy used for depression and anxiety

→ **Do not receive Sunlenca and tell your doctor immediately** if you think this applies to you.

Warnings and precautions

Talk to your doctor before using Sunlenca

- **Talk to your doctor or pharmacist if you have ever had severe liver disease, or if tests have shown problems with your liver.** Your doctor will carefully consider whether to treat you with Sunlenca.

While you are using Sunlenca

Once you start using Sunlenca, look out for:

- **Signs of inflammation or infection.**

→ **If you notice any of these symptoms, tell your doctor immediately.** For more information, see section 4, *Possible side effects*.

Regular appointments are important

It is important that you **attend your planned appointments** to receive your Sunlenca injection, to control your HIV infection, and to stop your illness from getting worse. Talk to your doctor if you are thinking about stopping treatment. If you are late receiving your Sunlenca injection, or if you stop receiving Sunlenca, you will need to take other medicines to treat your HIV infection and to reduce the risk of developing viral resistance.

Children and adolescents

Do not give this medicine to children under 18 years of age. The use of Sunlenca in patients aged under 18 has not yet been studied, so it is not known how safe and effective the medicine is in that age group.

Other medicines and Sunlenca

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Sunlenca may interact with other medicines. This may keep Sunlenca or other medicines from working properly, or may make side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels.

Medicines that must never be taken with Sunlenca:

- **rifampicin**, used to treat some bacterial infections, such as tuberculosis
- **carbamazepine, phenytoin**, used to prevent seizures
- **St. John's wort (*Hypericum perforatum*)**, a herbal remedy used for depression and anxiety

→ If you are taking any of these medicines, **do not receive Sunlenca injection and tell your doctor immediately.**

Talk to your doctor in particular if you are taking:

- antibiotics containing:
 - rifabutin
- anticonvulsants used to treat epilepsy and prevent seizures (fits), containing:
 - oxcarbazepine or phenobarbital
- medicines used to treat HIV, containing:
 - atazanavir/cobicistat, efavirenz, nevirapine, tipranavir/ritonavir or etravirine

- medicines used to treat migraine headache, containing:
 - dihydroergotamine or ergotamine
- medicine used to treat impotence and pulmonary hypertension, containing:
 - sildenafil or tadalafil
- medicine used to treat impotence, containing:
 - vardenafil
- corticosteroids (also known as ‘steroids’) taken orally or given by injection used to treat allergies, inflammatory bowel diseases, and other various illnesses involving inflammations in your body, containing:
 - dexamethasone or hydrocortisone/cortisone
- medicines used to lower cholesterol, containing:
 - lovastatin or simvastatin
- antiarrhythmics used to treat heart problems, containing:
 - digoxin
- medicines used to help you sleep, containing:
 - midazolam or triazolam.
- anticoagulants used to prevent and treat blood clots, containing:
 - rivaroxaban, dabigatran or edoxaban

→ **Tell your doctor if you are taking any of these medicines** or if you start taking any of these medicines during treatment with Sunlenca. Do not stop any treatment without contacting your doctor.

Sunlenca is a long-acting medicine. If after talking to your doctor you decide to stop your treatment or switch to another, you should know low levels of lenacapavir (the active substance in Sunlenca) can remain in your system for many months after your last injection. These low remaining levels should not affect other antiretroviral medicines that you take afterwards to treat your HIV infection. Some other medicines however may be affected by the low levels of lenacapavir in your system if you take them within 9 months after your last Sunlenca injection. You should check with your doctor if such medicines are safe for you to take after you stop treatment with Sunlenca.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As a precautionary measure you should avoid the use of Sunlenca during pregnancy unless your doctor tells you otherwise.

Breast-feeding is not recommended in women living with HIV because HIV infection can be passed on to the baby through breast milk. If you are breast-feeding, or thinking about breast-feeding, **you should discuss it with your doctor as soon as possible.**

Driving and using machines

Sunlenca is not expected to have any effect on your ability to drive or use machines.

Sunlenca contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per injection, that is to say essentially ‘sodium-free’.

3. How Sunlenca is given

Sunlenca is **used in combination with other antiretroviral medicines** to treat HIV infection. Your doctor will advise which other medicines you need to take to treat your HIV infection, and when you need to take them.

Your treatment with Sunlenca starts with tablets you take by mouth, followed by injections given by your doctor or nurse, as described below.

Talk to your doctor before taking the tablets. You will be advised when to start your tablets and when your appointment for the first injections will be scheduled.

Day 1 of treatment:

- Two tablets taken by mouth. These can be taken with or without food.

Day 2 of treatment:

- Two tablets taken by mouth. These can be taken with or without food.

Day 8 of treatment:

- One tablet taken by mouth. This can be taken with or without food.

Day 15 of treatment:

- Two injections into your abdomen (tummy) given at the same time by your doctor or nurse.

Every 6 months:

- Two injections into your abdomen given at the same time by your doctor or nurse.

If you are given more Sunlenca injection than you should

Your doctor or a nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or a nurse.

If you miss a Sunlenca injection

- It is important that you **attend your planned appointments every 6 months** to receive your injections of Sunlenca. This will help to control your HIV infection and to stop your illness from getting worse.
- If you think you will not be able to attend your appointment for your injections, call your doctor as soon as possible to discuss your treatment options.

If you miss or vomit the tablets, refer to the package leaflet for Sunlenca tablets.

If you stop receiving Sunlenca

Do not stop receiving Sunlenca without talking to your doctor. Keep receiving Sunlenca injections for as long as your doctor recommends. Stopping Sunlenca can seriously affect how future HIV treatments work.

→ **Talk to your doctor if you want to stop receiving Sunlenca injections.**

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects: tell a doctor immediately

- **Any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after HIV treatment is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines for HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
 - muscle weakness
 - weakness beginning in the hands and feet and moving up towards the trunk of the body
 - palpitations, tremor or hyperactivity

→ If you notice these or any symptoms of inflammation or infection, **tell your doctor immediately.**

Very common side effects

(may affect more than 1 in 10 people)

- **Reactions where Sunlenca is injected.**
Symptoms may include:
 - pain and discomfort
 - a hardened mass or lump
 - inflammatory reaction such as redness, itching, and swelling

Common side effects

(may affect up to 1 in 10 people)

- **Feeling sick** (nausea)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the *Yellow Card Scheme*, Website: www.mhra.gov.uk/yellowcard or search for *MHRA Yellow Card* in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sunlenca

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

6. Contents of the pack and other information

What Sunlenca contains

The active substance is lenacapavir. Each single-use vial contains 463.5 mg of lenacapavir.

The other ingredients are

Macrogol (E1521), water for injections.

What Sunlenca looks like and contents of the pack

Sunlenca solution for injection (injection) is a clear, yellow to brown solution with no visible particles. Sunlenca comes in two glass vials, each containing 1.5 ml of solution for injection. These vials are included in a dosing kit also containing 2 vial access devices (a device that will allow your doctor or a nurse to withdraw Sunlenca from the vial), 2 disposable syringes and 2 injection needles.

Marketing Authorisation Holder

Gilead Sciences Ltd
280 High Holborn
London
WC1V 7EE
United Kingdom

Manufacturer

Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:





Gilead Sciences Ltd
Tel: + 44 (0) 8000 113 700

This leaflet was last revised in 07/2023.

The following information is intended for healthcare professionals only:

Instructions for Use-Sunlenca 464 mg solution for injection

Your pack contains


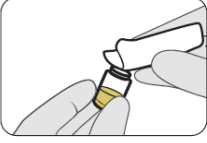
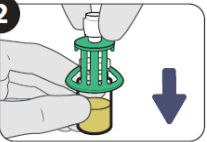
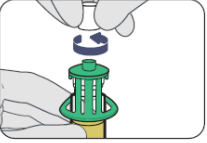
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2 vials access devices	
2 syringes	
2 injection needles	

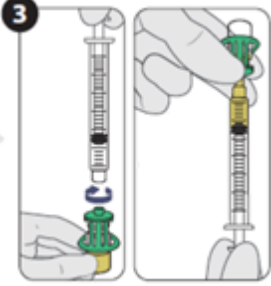
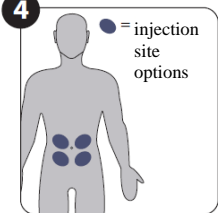
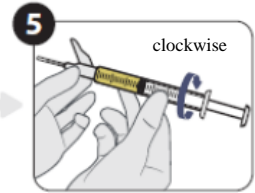
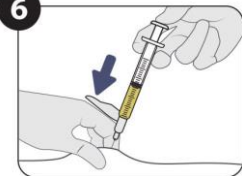
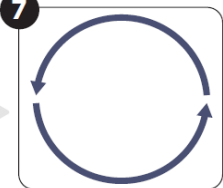
All the components are for single use.

A complete dose requires **two 1.5 mL injections**. The use of **the vial access device** is required.

Make sure that:

- Vial contains a **yellow-to-brown solution** with **no particles**
- Contents are **not damaged**
- Product is **not expired**

1. Prepare Vial	
	Remove cap.
	Clean vial stopper with alcohol wipe.
2. Prepare Vial Access Device	
	Push Down.
	Twist off.

<p>3. Attach and Fill Syringe</p> 	<ul style="list-style-type: none"> • Attach syringe and inject 1.5 mL of air into vial. • Flip upside down and withdraw all contents.
<p>4. Prepare an Injection Site on Patient's Abdomen</p> 	<p>Injection site options (at least 5 cm from navel)</p>
<p>5. Assemble needle and Syringe</p> 	<p>Attach Injection Needle and Prime to 1.5 mL</p>
<p>6. Inject Dose</p> 	<p>Inject 1.5 mL of Sunlenca Subcutaneously</p>
<p>7. Administer 2nd Injection</p> 	<p>Repeat steps for 2nd injection at new injection site.</p>